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EXAMINER	
JUNG, UNSU	
ART UNIT	**PAPER NUMBER**
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,499	GUZMAN, NORBERTO A.	
	Examiner	Art Unit	
	Unsu Jung	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-321* is/are pending in the application.

4a) Of the above claim(s) *40-321* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/5/03* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/27/05 & 9/19/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments to the specification in the reply filed on June 8, 2004 have been acknowledged and entered.

2. Applicant's amendments to the specification in the reply filed on October 12, 2004 have been acknowledged and entered.

Election/Restrictions

3. Applicant's election without traverse of Group I (claims 1-39) in the reply filed on September 9, 2005 is acknowledged.

Information Disclosure Statement

4. The information disclosure statement filed on May 27, 2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

A concise explanation of the relevance for WO 97/11362 is missing.

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference numbers 52 (Fig.'s 2, 4, and 6), 26 (Fig. 4), 92 (Fig.'s 7 and 8), 66A (Fig. 14), 37A (Fig. 15), 17A (Fig. 16), 13 (Fig. 18), 170 (Fig. 23B), 140A (Fig. 24A), 150A (Fig. 24A), 160A (Fig. 24A), 170A (Fig. 24B) are not described in the current specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to because reference number 46 in Fig. 6 is not referring to the same detector in Fig. 1. It is suggested that applicant change reference number 46 in Fig. 6 to "86." Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures

appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities: The use of the word "figure" is inconsistent throughout the specification. For example on p28, paragraph [0120], line 5, the word "figures" is capitalized, on 28, paragraph [0119], line 2, the word "figure is abbreviated as "Fig.", and on p25, paragraph [0113], line 9, the word "figure" is abbreviated and capitalized.

Appropriate correction is required.

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction

of the following is required: the specification fails to disclose the claimed subject matter in claim 36, which recites an apparatus, where the analyte concentrator has a transport port adapted to couple to the transport capillary and a separation port adapted to couple to the separation capillary, where the transport and separation ports intersect to form a concentration area to retain the affinity ligands.

9. The use of the trademarks MILLI-Q® (p43, line 2), BLUE CARRIER® (p43, line 9 p44, paragraph [0162], line 3 and p45, paragraph [0163], line6), SUPERDEX™ (p43, line 19 and p45, paragraph [0163], line 1), SEP-PAK® (p43, line 23 and p47, paragraph [0170], line 4), SEPHAROSE™ (p43, paragraph [0156], line 20 and p45 paragraph [0163], line 1), TEFLON® (p46, paragraph [0170], line 3), and PEEK™ (p46, paragraph [0170], line 3 and p47, paragraph [0170], line 7) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

10. Claim 2 is objected to because of the following informalities: a comma is needed following the phrase "the first position" in line 2 and "the second" in line 3. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 2, 6, 7, 11, 18, 19, 30, 31, 37, and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claim 2 recites the limitation "the second" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is suggested that applicant add "position" following the phrase "the second."

14. In claims 6 and 7, the word "interconnected" is vague and indefinite. The specification does not define the word and it is not clear what the word "interconnected" means.

15. Claim 11 recites the limitation "the sensitivity and selectivity" in line 5. There is insufficient antecedent basis for this limitation in the claim.

16. In claim 18, the term "simple solution" in line 3 is vague and indefinite. The specification defines the term "simple solution" as a solution having reduced number of

chemical and/or biochemical compounds relative to "complex solution" (p36, paragraph [0136]). However, the specification fails to clearly define the number of chemical and/or biochemical compounds in either "simple solution" or "complex solution." Therefore, it is unclear what the term "simple solution" means.

17. In claim 19, the term "complex solution" in line 3 is vague and indefinite. The specification defines the term "complex solution" as a solution having greater number of chemical and/or biochemical compounds relative to "simple solution" (p36, paragraph [0136]). However, the specification fails to clearly define the number of chemical and/or biochemical compounds in either "simple solution" or "complex solution." Therefore, it is unclear what the term "complex solution" means.

18. Claim 30 recites the limitation "the immobilized affinity ligands" in line 1. There is insufficient antecedent basis for this limitation in the claim.

19. Claim 31 recites the limitation "the immobilized affinity ligands" in line 1. There is insufficient antecedent basis for this limitation in the claim.

20. Claim 37 recites the limitation "the concentration area" in line 1. There is insufficient antecedent basis for this limitation in the claim.

21. Claim 38 recites the limitation "the concentration area" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. Claims 1-4, 8-13, 16, 18-23, 29, 31-36, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (U.S. Patent No. 6,150,180, Filed June 28, 1996) in view of Lipshutz et al. (U.S. Patent No. 5,856,174, Filed June 29, 1995).

Parce et al. teaches an electrophoresis apparatus comprising a transport capillary (sample injection channel) capable of directing flow of a sample solution to be analyzed (column 16, lines 8-20 and reference 304 in Fig. 3), a plurality of separation

capillaries (reaction channels) coupled to the transport capillary forming a plurality of analyte concentrators having affinity ligands capable of attracting at least one analyte of interest from the sample solution that passes through each of the analyte concentrators (column 16, lines 49-65). Parce et al. further teaches that once the sample solution (test compound) is in a position adjacent to the intersection (analyte concentrator) of the parallel reaction channel (separation capillary) and the sample injection channel (transport capillary), the sample solution is directed into its respective reaction channel by redirecting fluid flow (column 16, line 66-column 17, line 2), which can be controlled by a variety of devices including valves (column 17, lines 32-35). However, Parce et al. fails to specifically teach a plurality of valves located on the transport capillary and on the plurality of separation capillaries, where the valves on the transport capillary control the flow of the sample solution through the transport capillary and the valves on the plurality of separation capillaries control the flow of fluid through each of the plurality of separation capillaries, whereby each of the analyte concentrators can be localized by the valves on the transport and the plurality of separation capillaries.

Lipshutz et al. teaches a device comprising a plurality of fluid passages, which include a valve disposed across the fluid passage, whereby the fluid passages may be selectively opened and closed to direct fluid sample (column 2, lines 62-65). Specifically, Lipshutz et al. teaches a method of using valves to provide fluid direction in fluid channels, which allow for the transportation of samples (column 4, lines 38-45). Furthermore, Lipshutz et al. teaches that a reaction chamber may be provided with an

inlet/outlet valve structure for sealing the reaction chamber to retain a fluid sample therein (column 16, lines 42-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the electrophoresis apparatus of Parce et al. with a reaction chamber (analyte concentrator) provided with an inlet/outlet valve structure as taught by Lipshutz et al. in order to seal the reaction chamber to retain a fluid sample therein.

With respect to claim 2, Parce et al. teaches a use of switching valves (column 12, line 21), which would inherently be movable to allow the fluid to flow through the respective capillary or to substantially prevent the flow of fluid through the respective capillary.

With respect to claims 3 and 4, Parce et al. teaches the apparatus of claim 1, further including a matrix-assembly in each of the analyte concentrators, where at least one of the affinity ligands in each of the analyte concentrator is bound to the surface of the matrix-assembly, which is a plurality of microstructures such as beads (column 16, lines 49-59).

With respect to claim 8, Parce et al. teaches the apparatus of claim 1, wherein each of the separation capillaries is capable of separating at least one analyte retained by at least one of the affinity ligands after the analyte is released from the at least one affinity ligands.

With respect to claim 9, Parce et al. teaches the apparatus of claim 8, where each of the separation capillaries is capable of separating at least one of the released

analyte from the affinity ligands by at least one mode of capillary electrophoresis (column 15, line 55-column 16, line 3).

With respect to claim 10, Parce et al. teaches the apparatus of claim 1, where each of the separation capillaries has an inlet and an outlet, where the analyte concentrator for the respective separation capillary is between the inlet and the outlet, further including an auxiliary capillary (306 in Fig. 3) coupled to the respective separation capillary between the analyte concentrator and the outlet to provide a second fluid to the respective capillary away from the analyte concentrator (Fig. 3).

With respect to claim 11, Parce et al. teaches the apparatus of claim 1, further including an auxiliary analyte concentrator having affinity ligands capable of retaining chromophores to bind to the at least one analyte of interest released from the analyte concentrator to improve sensitivity and selectivity of the analyte of interest (column 13, lines 48-65).

With respect to claim 12, Parce et al. teaches the apparatus of claim 1, wherein each of the separation capillaries is hollow and filled with electrically conductive fluid (column 15, lines 60-65).

With respect to claim 13, Parce et al. teaches the apparatus of claim 1, where each of the separation capillaries is hollow and filled with a gel matrix and an electrically conductive fluid (column 15, lines 60-65 and column 17, lines 25-29).

With respect to claim 14: (column 21, lines 31-35)

With respect to claim 16, Parce et al. teaches the apparatus of claim 1, where each of the separation capillaries is in a linear configuration (Fig. 3).

With respect to claims 18 and 19, Parce et al. teaches the apparatus of claim 1, where the affinity ligands in each of the analyte concentrators are immobilized and are capable of purifying at least one analyte present in a simple or complex solution (column 16, lines 49-59).

With respect to claims 20 and 22, Parce et al. teaches the apparatus of claim 1, where the affinity ligands in each of the analyte concentrators are immobilized and are capable of performing a biochemical reaction (column 4, lines 40-55).

With respect to claims 21 and 23, Parce et al. teaches the apparatus of claim 1, where the affinity ligands in each of the analyte concentrators are immobilized and are capable of performing multi-component biochemical reactions (column 13, line 48-column 14, line 17).

With respect to claim 29, Parce et al. teaches the apparatus of claim 1, where two adjacent transport capillaries are staggered at each of the analyte concentrators (Fig. 5 and Fig. 6A).

With respect to claim 31, Parce et al. teaches the apparatus of claim 1, where the immobilized affinity ligands in each of the analyte concentrators attract at least one analyte of interest from the sample solution having a range of concentrations (column 6, lines 16-39).

With respect to claim 32, Parce et al. teaches the apparatus of claim 1, further including an outlet capillary near a detection area, where the plurality of separation capillaries merge at the outlet capillary (Fig. 4).

With respect to claims 33 and 34, Parce et al. teaches the apparatus of claim 1, further including at least one detection system (fluorescence) for identifying, quantifying, and characterizing the analyte of interest released from the affinity ligands and passing through at least one of the plurality of separation capillaries (column 10, lines 11-23).

With respect to claim 35, Parce et al. teaches the apparatus of claim 1, where the analyte concentrator is a microextraction device using immobilized affinity ligands within the microextraction device (column 12, lines 17-18).

With respect to claim 36, Parce et al. teaches the apparatus of claim 1, where the analyte concentrator has a transport port adapted to couple to the transport capillary and a separation port adapted to couple to the separation capillary, where the transport and separation ports intersect to form a concentration area to retain affinity ligands (Fig. 3).

With respect to claim 38, Lipshutz et al. teaches a plurality of valves movably coupled to surround the concentration area (reaction chamber) to control the flow of the sample solution through the transport and separation ports (column 16, lines 42-45).

With respect to claim 39, Parce et al. teaches the apparatus of claim 1, where the transport and separation capillaries having openings, where the openings for the transport capillary is larger than the openings for the separation capillaries (Fig. 3).

25. Claims 5, 6, 14, 15, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (U.S. Patent No. 6,150,180, Filed June 28, 1996) in view of Lipshutz et al. (U.S. Patent No. 5,856,174, Filed June 29, 1995) as applied to claims

1 and 3 above, and further in view of Nelson et al. (U.S. Patent No. 6,007,690, Filed July 30, 1997).

Parce et al. in view of Lipshutz et al. teaches an electrophoresis apparatus as discussed above. However, Parce et al. in view of Lipshutz et al. fails to teach an electrophoretic apparatus, where the analyte concentrator retains the matrix assembly by pressure-resistant porous end walls disposed in the transport capillary and the separation capillary.

Nelson et al. teaches integrated microfluidic devices comprising at least an enrichment channel (analyte concentrator) and a main electrophoretic flow path for use in a variety of electrophoretic applications (Abstract and Fig. 1). Nelson further teaches various enrichment channel means including glass frits or plugs of agarose gel employed to cover the fluid outlets or inlets, where frits or plugs allow for fluid flow but not for particle or other insoluble matrix flow out of the enrichment channel (column 5, line 65-column 6, line 6). The enrichment channel serves to selectively retain and separate target analyte comprising fraction from the remaining components or the waste portion of the initial sample volume (column 4, lines 50-53).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the apparatus of Parce et al. in view of Lipshutz et al. with an analyte concentrator chamber design of Nelson et al., which allows for fluid flow but not for particle or other insoluble matrix flow out of the analyte concentrator, in order to selectively retain and separate target analyte comprising fraction from the remaining components or the waste portion of the initial sample volume.

With respect to claim 6, Nelson et al. teaches a matrix assembly, which includes interconnected beads, which is disclosed by the current specification (p19, paragraph [0101]) as beads coated with binding members (affinity ligands) such as lectin, enzyme, cofactor, Protein A, antibody, antigen, and oligonucleotide (column 5, lines 50-65).

With respect to claims 14 and 15, Nelson et al. teaches an electrophoretic flow path with branches of affinity zones (column 17, lines 48-57). Pertinent properties of milieu including temperature can advantageously be controlled in each flow path branch independently of the others (column 17, lines 57-62). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the apparatus of Parce et al. in view of Lipshutz et al. with each flow path branch having an independent temperature control for use in a variety of electrophoretic applications.

With respect to claim 28, Nelson et al. teaches that affinity ligands in each of the analyte concentrators are covalently bound to a matrix assembly within the analyte concentrator (column 5, lines 50-56).

With respect to claim 30, Nelson et al. teaches an analyte concentrator, where the immobilized affinity ligands are bound to a portion of the inner wall of the separation capillary (column 5, lines 50-65).

26. Claims 5, 7, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (U.S. Patent No. 6,150,180, Filed June 28, 1996) in view of Lipshutz et al. (U.S. Patent No. 5,856,174, Filed June 29, 1995) as applied to claims 1 and 3 above,

and further in view of Heegaard et al. (Journal of Chromatography B, Sept. 1998, Vol. 715, pp29-54).

Parce et al. in view of Lipshutz et al. teaches an electrophoresis apparatus as discussed above. However, Parce et al. in view of Lipshutz et al. fails to teach an electrophoretic apparatus, where the analyte concentrator retains the matrix assembly by pressure-resistant porous end walls disposed in the transport capillary and the separation capillary.

Heegaard et al. teaches a technique of on-line solid phase extraction capillary electrophoresis utilizing various stationary phases and a wide variety of chemistries for immobilization of ligands (p43, left column, lines 26-36 and Fig. 13). Specifically, Heegaard et al. teaches an analyte concentrator containing immobilized antibodies bound directly to the surface of controlled porous glass beads, wherein the beads were embraced between two frits (porous end walls) forming a micro-affinity column (Fig. 17). This enrichment chamber design permits a larger surface area capacity, enabling a 200- to 5000-fold increase in analyte detectability.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the apparatus of Parce et al. in view of Lipshutz et al. with an analyte concentrator chamber design of Heegaard et al. in order to permit a larger surface area capacity, enabling a 200- to 5000-fold increase in analyte detectability.

With respect to claim 6, Heegaard et al. teaches an analyte concentrator chamber, where the matrix assembly includes a fixed architecture that is defined by beaded microstructures

With respect to claim 7, Heegaard et al. teaches an analyte concentrator, where the matrix assembly includes a fixed architecture that is fabricated from polymeric microstructures interconnected to each other and to a portion of the separation capillary (Fig. 10).

With respect to claim 30, Heegaard et al. teaches an analyte concentrator, where the immobilized affinity ligands are bound to a portion of the inner wall of the separation capillary (Fig. 13A and Fig. 14)

27. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (U.S. Patent No. 6,150,180, Filed June 28, 1996) in view of Lipshutz et al. (U.S. Patent No. 5,856,174, Filed June 29, 1995) as applied to claim 1 above, and further in view of Ogan et al. (U.S. Patent No. 4,816,123, Filed Apr. 16, 1986).

Parce et al. in view of Lipshutz et al. teaches an electrophoresis apparatus as discussed above. Parce et al. further teaches methods of maximizing the use of space on a substrate, serpentine, saw tooth or other channel geometries, to incorporate effectively longer channels in shorter distances. However, Parce et al. in view of Lipshutz et al. fails to teach an electrophoretic apparatus, where each of the separation capillaries is in coiled configuration.

Ogan et al. teaches a method of fabricating capillary electrophoresis separation channels (Abstract). Ogan et al. teaches that a long length of capillary could be contained in the same external length by coiling the template in a helical shape.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the apparatus of Parce in view of Lipshutz et al. with a long length of capillary contained in the same external length by coiling the template in a helical shape as taught by Ogan et al. in order to maximize the use of space on a substrate to incorporate effectively longer channels in shorter distances.

28. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (U.S. Patent No. 6,150,180, Filed June 28, 1996) in view of Lipshutz et al. (U.S. Patent No. 5,856,174, Filed June 29, 1995) as applied to claim 1 above, and further in view of Yeung et al. (U.S. Patent No. 5,324,401, Filed Feb. 5, 1993).

Parce et al. in view of Lipshutz et al. teaches an electrophoresis apparatus as discussed above. However, Parce et al. in view of Lipshutz et al. fails to teach an electrophoretic apparatus, where each of the analyte concentrators has an encapsulated subcellular structure to carry drug metabolism studies.

Yeung et al. teaches a capillary electrophoresis apparatus, which is used for separation and measurement of the species present in samples of biological, ecological, or chemical interest (column 14, lines 7-9). Of particular interest are macromolecules, genetic materials, and cellular materials such as bacteria, viruses, organelles, cell

fragments, metabolites, drugs, and the like and combinations thereof (column 14, lines 9-15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the apparatus of Parce et al. in view of Lipshutz et al. with a method of using the electrophoresis apparatus of Parce et al. in view of Lipshutz et al. to separate cellular materials such as bacteria, viruses, organelles, and cell fragments as taught by Yeung et al. in order for measurement of the species present in samples of biological, ecological, or chemical interest.

29. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (U.S. Patent No. 6,150,180, Filed June 28, 1996) in view of Lipshutz et al. (U.S. Patent No. 5,856,174, Filed June 29, 1995) as applied to claim 1 above, and further in view of Yamanishi et al. (U.S. PG Pub. No. US 2003/0134416 A1, Filed Oct. 11, 2001).

Parce et al. in view of Lipshutz et al. teaches an electrophoresis apparatus as discussed above. However, Parce et al. in view of Lipshutz et al. fails to teach an electrophoretic apparatus, where each of the analyte concentrators has an acoustic micromixing system to improve the reaction in the analyte concentrators.

Yamanishi et al. teaches filtration chamber comprising acoustic elements to apply physical forces to promote, enhance, or facilitate processing or desired biochemical reactions of a sample (pp14-15, paragraph [0169]). For example, acoustic elements can cause mixing of the components within the chamber, thereby dislodging nonfilterable components from the slots or pores (p14, paragraph [0169], lines 16-19).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the apparatus of Parce et al. in view of Lipshutz et al. with acoustic element of Yamanishi et al. in order to promote, enhance, or facilitate processing or desired biochemical reactions of a sample by mixing of the components within the analyte concentrators of Parce et al. in view of Lipshutz et al.

30. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (U.S. Patent No. 6,150,180, Filed June 28, 1996) in view of Lipshutz et al. (U.S. Patent No. 5,856,174, Filed June 29, 1995) as applied to claim 1 above, and further in view of Barenburg et al. (U.S. PG Pub. No. US 2002/0115201 A1, Filed Sept. 16, 1999).

Parce et al. in view of Lipshutz et al. teaches an electrophoresis apparatus as discussed above. However, Parce et al. in view of Lipshutz et al. fails to teach an electrophoretic apparatus, where each of the analyte concentrators has a microwave pulse system to improve the reaction in the analyte concentrators.

Barenburg et al. teaches a microwave radiation device, which is applied to chemical reactions and processes, including nucleic acid extraction from microorganisms, enhances, or sometimes make possible the desired result (p2, paragraph [0010]). Thus, there is a need in the art for microfluidic devices in which microwave radiation can be applied to the reaction cavities within the device (p2, paragraph [0010]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the apparatus of Parce et al. in view of Lipshutz et al.

with a microwave integrated circuit for applying microwave radiation to a cavity within a microfluidic device as taught by Barenburg et al. in order to enhance or sometimes make possible the desired result of chemical reactions and processes, in including nucleic acid extraction.

31. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (U.S. Patent No. 6,150,180, Filed June 28, 1996) in view of Lipshutz et al. (U.S. Patent No. 5,856,174, Filed June 29, 1995) as applied to claims 1, 35, and 36 above, and further in view of Fuchs et al. (U.S. Patent No. 5,246,577, Filed May 29, 1990).

Parce et al. in view of Lipshutz et al. teaches an electrophoresis apparatus as discussed above. However, Parce et al. in view of Lipshutz et al. fails to teach an electrophoretic apparatus, where the concentration area is surrounded by bulging members to retain the matrix containing immobilized affinity ligands within the concentration area.

Fuchs et al. teaches an apparatus for concentrating a solute sample, which can be subsequently released for analysis by capillary electrophoresis (Abstract). The apparatus comprises a capillary tube containing a short length of packed particles or gel adapted to retain sample solutes, which particles are retained in the capillary tube by constrictions (concentration area surrounded by bulging members, Abstract and Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the apparatus of Parce et al. in view of Lipshutz et al. with the apparatus having a concentration area with constricted regions as taught by

Fuchs et al. in order to retain packed particles or gel adapted and sample solutes in the capillary tube.

Double Patenting

32. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

33. Claims 1-9, 12, 13, 16, 20-23, and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,406,604 in view of Lipshutz et al. (U.S. Patent No. 5,856,174, Filed June 29, 1995).

U.S. Patent No. 6,406,604 teaches an electrophoresis apparatus comprising a transport capillary capable of directing flow of a sample solution to be analyzed, a plurality of separation capillaries coupled to the transport capillary forming a plurality of analyte concentrators having affinity ligands capable of attracting at least one analyte of interest from the sample solution that passes through each of the analyte concentrators.

However, U.S. Patent No. 6,406,604 fails to specifically teach a plurality of valves located on the transport capillary and on the plurality of separation capillaries, where the valves on the transport capillary control the flow of the sample solution through the transport capillary and the valves on the plurality of separation capillaries control the flow of fluid through each of the plurality of separation capillaries, whereby each of the analyte concentrators can be localized by the valves on the transport and the plurality of separation capillaries.

Lipshutz et al. teaches a device comprising a plurality of fluid passages, which include a valve disposed across the fluid passage, whereby the fluid passages may be selectively opened and closed to direct fluid sample (column 2, lines 62-65). Specifically, Lipshutz et al. teaches a method of using valves to provide fluid direction in fluid channels, which allow for the transportation of samples (column 4, lines 38-45). Furthermore, Lipshutz et al. teaches that a reaction chamber may be provided with an inlet/outlet valve structure for sealing the reaction chamber to retain a fluid sample therein (column 16, lines 42-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the electrophoresis apparatus of U.S. Patent No. 6,406,604 with a reaction chamber (analyte concentrator) provided with an inlet/outlet valve structure as taught by Lipshutz et al. in order to seal the reaction chamber to retain a fluid sample therein.

34. Claims 1, 2 and 33 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33 and 34 of copending Application No. 10/821,328 in view of Lipshutz et al. (U.S. Patent No. 5,856,174, Filed June 29, 1995).

Copending application teaches an electrophoresis apparatus comprising a transport capillary capable of directing flow of a sample solution to be analyzed, a plurality of separation capillaries coupled to the transport capillary forming a plurality of analyte concentrators having affinity ligands capable of attracting at least one analyte of interest from the sample solution that passes through each of the analyte concentrators. However, copending application fails to specifically teach a plurality of valves located on the transport capillary and on the plurality of separation capillaries, where the valves on the transport capillary control the flow of the sample solution through the transport capillary and the valves on the plurality of separation capillaries control the flow of fluid through each of the plurality of separation capillaries, whereby each of the analyte concentrators can be localized by the valves on the transport and the plurality of separation capillaries.

Lipshutz et al. teaches a device comprising a plurality of fluid passages, which include a valve disposed across the fluid passage, whereby the fluid passages may be selectively opened and closed to direct fluid sample (column 2, lines 62-65). Specifically, Lipshutz et al. teaches a method of using valves to provide fluid direction in fluid channels, which allow for the transportation of samples (column 4, lines 38-45). Furthermore, Lipshutz et al. teaches that a reaction chamber may be provided with an

inlet/outlet valve structure for sealing the reaction chamber to retain a fluid sample therein (column 16, lines 42-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the electrophoresis apparatus of copending application with a reaction chamber (analyte concentrator) provided with an inlet/outlet valve structure as taught by Lipshutz et al. in order to seal the reaction chamber to retain a fluid sample therein.

This is a provisional obviousness-type double patenting rejection.

Conclusion

35. No claim is allowed.

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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